K122096

STORZ
Karl Storz Endoscopy

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document are accurate and complete to the best of KSEA's knowledge.

SEP 27 2012

Submitter: Karl Storz Endoscopy-America, Inc.
2151 E. Grand Avenue
El Segundo, CA 90245-5017
Phone: (424) 218-8381
Fax: (424) 218-8519

Contact Person: Leigh Spotten
Regulatory Affairs Manager
Email: leigh.spotten@karlstorz.com

Date Prepared: July 13, 2012

Device Trade Name: Karl Storz Navigation Panel Unit (NPU) System

Common Name: Image Guided Surgery System

Classification Name: Neurologic stereotaxic instrument

Regulation Number: 21 CFR 882.4560

Product Code: HAW

Predicate Device(s):
BrainLAB AG: Kolibri Image Guided Surgery System (K014256)

Device Description:
The Karl Storz Navigation Panel Unit (NPU) System is a multi-component system to be used as a positioning aid for navigation in ENT surgery. The software comprises a planning and treatment program in which an instrument is navigated on the basis of pre-loaded radiological image data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 27 2012

Karl Storz Endoscopy-America, Inc.
c/o Mr. Leigh Spotten
Regulatory Affairs Manager
2151 E. Grand Ave.
El Segundo, CA 90245-5017

Re: K122096
Trade/Device Name: Navigation Panel Unit System (NPU)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: July 13, 2012
Received: July 16, 2012

Dear Mr. Spotten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122096

Indication for use

510(k) Number (if known): K122096

Device Name: Navigation Panel Unit System (NPU)

Indications for use: The Navigation Panel Unit System (NPU) is an intraoperative image guided localization system that links a freehand probe tracked by a passive marker sensor system to a virtual computer image space on a patient's preoperative diagnostic image data set. The system is intended to be used as a positioning aid for navigation in ENT surgery, including but not limited to endoscopic surgery. The NPU is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure can be identified relative to the radiological imaging-based model of the anatomy. Surgery procedures include but are not limited to the following: transphenoidal procedures, maxillary antrostomies, ethmoidectomies, sphenoidectomies, sphenoid explorations, turbinate resections, frontal sinusotomies, intranasal procedures, intranasal tumor resections, otologic surgery, and ENT skull base surgery.

Prescription Use ✓ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K122096